

## REMARKS

Claims 1, 22, 30, 43, and 51 have been amended, and claim 29 was previously cancelled. Thus, claims 1-28 and 30-54 are pending in the present application. The claim amendments are supported by the specification and drawings as originally filed, with no new matter being added. Accordingly, favorable reconsideration of the pending claims is respectfully requested.

Applicants thank the Examiner for the courtesy of a telephone interview on September 2, 2004. Proposed amendments to claims 1, 22, 43, and 51 were discussed, which correspond to the amendments for these claims presented herein. The Examiner indicated that further consideration and a search would be required in relation to the proposed amendments.

### 1. Rejections Under 35 U.S.C § 102

Claims 1-5, 8-11, 13-18, 20-28, 30-32, and 43-50 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,964,482 to Gerstel et al. (hereafter "*Gerstel*") for the reasons stated on pages 2-5 of the Office Action. Applicants respectfully traverse.

Claim 1 has been amended to recite that "the microneedles are located on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface." Support for this limitation can be found in Figure 1 of the present application, where microneedles 16 are located on major surface 14 of substrate 12 such that microneedles 16 extend in a direction substantially parallel to major surface 14.

In contrast, *Gerstel* discloses that projections 12 extend outwardly from a major surface so that projections 12 are perpendicular to the major surface, as shown in Figures 1-4. There is no teaching or suggestion in *Gerstel* that the projections 12 could be formed such that they are parallel to the major surface on which they are located. Thus, claim 1, as well as the rejected dependent claims therefrom, are not anticipated by or obvious over *Gerstel*.

Independent claim 22 has been amended to recite “at least one first structural support member that interconnects the microneedles adjacent the proximal end of the microneedles” and “at least one second structural support member that interconnects the microneedles adjacent the distal end of the microneedles.” Support for these limitations can be found in Figures 2A and 2B of the present application, where a pair of structural support members 38 interconnect with microneedles 32 adjacent the proximal and distal ends of microneedles 32.

In contrast, *Gerstel* discloses that projections 12 are formed on a surface of a drug reservoir 16 that interconnects the projections 12 (*see* Figures 1-4). There is no teaching or suggestion in *Gerstel* of a “second structural support member that interconnects the microneedles adjacent the distal end of the microneedles” as recited in claim 22. Hence, claim 22, as well as the rejected dependent claims therefrom, are not anticipated by or obvious over *Gerstel*.

Independent claim 43 recites a microneedle device comprising a “single” hollow elongated shaft comprised of a non-silicon material. Support for the recitation of a “single” hollow microneedle can be found in Figure 3 and on page 6, lines 21-23 of the present application.

There is no teaching or suggestion in *Gerstel* of a “single” hollow elongated shaft as recited in claim 43. Rather, *Gerstel* discloses only a plurality of projections 12 (*see* Figures 1-4). Thus, claim 43, as well as the rejected dependent claims therefrom, are not anticipated by or obvious over *Gerstel*.

Accordingly, for the foregoing reasons, Applicants respectfully request that the rejection of claims 1-5, 8-11, 13-18, 20-28, 30-32, and 43-50 under 35 U.S.C. § 102(b) be withdrawn.

Claims 51-53 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,728,392 to Miura et al. (hereafter “*Miura*”) for the reasons stated on page 5 of the Office Action. Applicants respectfully traverse.

Independent claim 51 has been amended to recite that “the microneedles are formed on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface” similar to claim 1.

In contrast, *Miura* discloses formation of a ring-shaped nozzle 32a that extend outwardly from a major surface of a substrate 31 so that the nozzle 32a is perpendicular to the major surface, as shown in Figures 8C and 8F. There is no teaching or suggestion in *Miura* that the nozzle 32a could be formed such that it is parallel to the major surface on which it is located.

In addition, claim 51 recites the limitation of “depositing a metal material to form side walls and a top wall upon the one or more bottom walls and around the photoresist layer.” There is no teaching or suggestion in *Miura* that a “top wall” is formed upon the one or more bottom walls and around the photoresist layer. Rather, *Miura* only discloses side walls for the nozzle 32a as shown in Figures 8C-8F.

Thus, claims 51-53 are not anticipated by or obvious over *Miura*. Accordingly, Applicants respectfully request that the rejection of claims 51-53 under 35 U.S.C. § 102(b) be withdrawn.

## 2. Rejections Under 35 U.S.C. § 103

Claims 12, 19, 33-42 and 54 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over *Gerstel* for the reasons stated on pages 5-6 of the Office Action. Applicants respectfully traverse.

Claims 12 and 19 depend from claim 1, and claim 54 depends from claim 22. Each of these dependent claims include the respective limitations of the corresponding independent claim, and thus would not have been obvious over *Gerstel* for at least the reasons set forth previously with respect to claims 1 and 22.

Independent claim 33 recites a microneedle device comprising a “single” hollow non-silicon microneedle on a planar surface of a substrate. As the Examiner admits, there is no teaching or suggestion in *Gerstel* of a “single” microneedle as recited in claim 33. Rather, *Gerstel* discloses only a plurality of projections 12 (see Figures 1-4). The Examiner states that since Applicants disclose the embodiments of both single and multiple hollow microneedles, these can be considered equivalents. Applicants respectfully disagree, and do not consider the single and multiple hollow microneedles to be equivalents.

Thus, claim 33, as well as the rejected dependent claims therefrom, would not have been obvious over *Gerstel*. Applicants therefore respectfully request that the rejection of claims 12, 19, 33-42 and 54 under 35 U.S.C. § 103(a) be withdrawn.

Claims 6 and 7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over *Getstel* in view of U.S. Patent No. 5,406,573 to Ozbay et al. (hereafter “*Ozbay*”) for the reasons stated on page 7 of the Office Action. Applicants respectfully traverse.

Claims 6 and 7 depend from claim 1 and include the limitations thereof. There is no teaching or suggestion in *Gerstel* of microneedles located on the major surface of the substrate such that the microneedles extend in a direction substantially parallel to the major surface as recited in claim 1. *Ozbay* also does not teach or suggest such a feature.

Thus, claims 6 and 7 would not have been obvious over *Gerstel* in view of *Ozbay*. Applicants therefore respectfully request that the rejection of claims 6 and 7 under 35 U.S.C. § 103(a) be withdrawn.

3. Double Patenting

Claims 51-53 were rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 5,876,582. In addition, claims 1-28 and 30-50 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-15 and 18-24 of U.S. Patent No. 5,871,158.

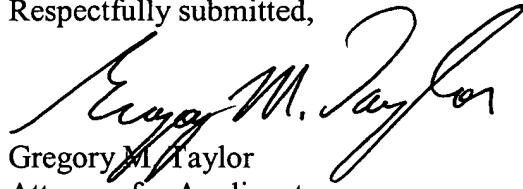
Applicants will submit a terminal disclaimer to overcome the double patenting rejections of the claims, once allowable subject matter is indicated.

### CONCLUSION

In view of the foregoing, Applicants respectfully request favorable reconsideration and allowance of the present claims. In the event there remains any impediment to allowance of the application, which could be clarified in a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney.

Dated this 17<sup>th</sup> day of September 2004.

Respectfully submitted,



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